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DOCKET NO: 204395US0X PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :  
YUKINO OWAKI, ET AL. : EXAMINER: GOLLAMUDI, S.  
SERIAL NO: 09/786,370 :  
FILED: MARCH 15, 2001 : GROUP ART UNIT: 1616  
FOR: TAPE MATERIAL FOR :  
TRANSCUTANEOUS ABSORPTION :

DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Now comes Naomi Ikeda who deposes and states that

1. I am familiar with the invention in the above-identified application.
2. I am a graduate of Sasebo National College of Technology Industrial Chemistry department and received my degree N.I.  
in the year 1979. Jan. 23, 2004
3. I have been employed by Yateku Pharmaceutical Ind. Co. since 1979 and I have been conducting research in the field of Transdermal absorption preparation for 15 years.
4. I have reviewed and understood the contents of U.S. Patent No. 5,827,528 (Kubo et. al.) which is cited by the Examiner as prior art against the claims of the above-identified application.
5. In order to demonstrate that the exclusion of water and water absorbing components from the claimed composition provides a composition that is different from adhesive compositions which contain water or a water absorbing component, the following experiments were carried out by me or under my direct supervision and control.

## 6. Experiment Report

Comparative tape preparations were each prepared by adding one of three water absorbing components, which are disclosed in Kubo et al. (U.S. 5,827,528), or water to an adhesive mass of the formulation described in Example 1 of U.S. Patent Application Serial No. 09/786,370. The comparative tape preparations and the tape preparation (invention tape preparation) described in Example 1 of U.S. Patent Application Serial No. 09/786,370 were tested for waterproofness. The results will be reported below.

### 1. Production of preparations to be tested

Tape preparations with adhesive masses of the formulations shown in Table 1 were produced, and then tested as will be described below in Item 2. It is to be noted that with respect to the individual ingredients contained in the adhesive mass for the invention preparation, their proportions were adjusted to give 100 parts by weight as the whole amount of the resulting adhesive mass.

Table 1 Formulations

Ingredients	Invention prepn.	Comparative Prepn. 1	Comparative Prepn. 2	Comparative Prepn. 3	Comparative Prepn. 4
Lidocaine	5.0	3.5	3.5	3.5	4.5
Styrene-isoprene-styrene block copolymer	22.0	15.4	15.4	15.4	19.8
Butyl rubber	5.0				
Aliphatic saturated hydrocarbon resin	32.9	3.5	3.5	3.5	4.5
Liquid paraffin		23.0	23.0	23.0	29.6
Titanium oxide	30.0	21.0	21.0	21.0	
Antioxidant	5.0	3.5	3.5	3.5	27.0
Carboxymethylcellulose CMC-1380	0.1	0.1	0.1	0.1	4.5
Gelatin	-	30.0	-	-	0.1
Karaya gum	-	-	30.0	-	-
Water	-	-	-	30.0	-
(unit: parts by weight)					10.0

The test of the preparation with karaya gum added therein was cancelled, because karaya gum particles were colored and appeared as spots on the surface of the adhesive mass and hence, the resultant preparation had a quality problem as a plaster. The test of the preparation with water added therein was also cancelled because water separated to fail in providing any homogenous adhesive mass.

## 2. Waterproofness test

Each preparation was cut into patches of 5 mm squares. Twenty (20) patches were adhered at random on the palm of the left hand. Subsequently, the hand was submerged in a constant-temperature water bath controlled at 37°C. The numbers of separated patches were counted at predetermined time intervals.

Incidentally, the hand was shaken in the constant-temperature bath after an elapsed time of 30 minutes since the initiation of the test with the hand submerged there, because not many patches separated until 30 minutes after the initiation of the test.

## (Results)

Table 2 Numbers of patches separated after individual time periods (minutes)

Tested preparations		Invention prepn.	Comparative prepn. 1	Comparative prepn. 2
Number of separated patches	5 min	0	1	0
	10 min	0	0	0
	15 min	0	0	0
	20 min	0	0	0
	25 min	0	0	0
	30 min	0	0	0
	40 min	1	0	0
	50 min	0	4	4
	60 min	0	11	2
	70 min	0	3	1
	80 min	0	1	2
	90 min	0	0	0
	Total	1	20	10

From the above results, the patches of the comparative preparations separated 10 to 20 times as much as those of the invention preparation. It has, therefore, been confirmed that the comparative preparations are considerably inferior in waterproofness to the invention preparation.

Further, karaya gum and water have the problems mentioned above in Item 1. Accordingly, none of the tested comparative preparations which were added with the water absorbing components and water, respectively, were usable.

7. From the above-described Experiment Report it is evident that the inclusion of water and/or a water <sup>absorbing</sup> ~~absorbent~~ component in the claimed composition affects the claimed <sup>M.I.</sup> ~~composition's~~ basic and novel characteristics. The inclusion of water or a water absorbing component negatively affects the ability of the claimed adhesive preparation to adhere to skin when immersed in water (i.e., waterproofness). JAN. 23, 2004

8. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to

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P. 8

true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

9. Further deponent sayeth not.

Naomi Ikeda  
Signature

January 23. 2004  
Date